

Application No. 10/049,167
Attorney Docket No. PJ3732USW

In the Claims:

1. (original) A pharmaceutical formulation which comprises an aqueous solution of carboxy methylcellulose sodium, glycerol, propylene glycol and polyoxyethylene (20) sorbitan monooleate, containing suspended therein particulate microcrystalline cellulose and beclomethasone dipropionate anhydrate, characterised in that said aqueous suspension further comprises:

Dextrose;
Phenylethyl alcohol;
Benzalkonium chloride;
Disodium hydrogen orthophosphate; and
Citric acid.

2. (original) A pharmaceutical formulation according to claim 1 characterised in that it is buffered to a pH of between 5 and 6.

3. (original) A pharmaceutical formulation according to claim 1 characterised in that it is isotonic with fluids of the nasal cavity.

4. (original) A pharmaceutical formulation according to claim 1 having a composition as follows:

Micronised beclomethasone dipropionate anhydrate	0.1% (w/w)
Dextrose anhydrous	5.0% (w/w)
Microcrystalline cellulose	
and carboxymethylcellulose sodium (Avicel RC591)	1.5% (w/w)
Phenylethyl alcohol	0.275% (v/w)
Benzalkonium chloride solution 50% (w/v)	0.04% (v/w)
Glycerol	4.0% (w/w)
Propylene glycol	1.0% (w/w)
Polyoxyethylene (20) sorbitan monooleate	0.007% (w/w)
Disodium hydrogen orthophosphate anhydrous	0.31% (w/w)
Citric acid monohydrate	0.2% (w/w)

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Purified water

to 100%.

5. (original) A container comprising a pharmaceutical formulation according to claim 1 suitable for delivering it in the form of a nasal spray.

6. (original) A pharmaceutical formulation according to claim 1 for use in the treatment or prophylaxis of allergic rhinitis.

7. (currently amended) A method for the manufacture of a medicament product useful in the treatment of prophylaxis of allergic rhinitis comprising the step of incorporating Use of a pharmaceutical formulation according to claim 1 in said medicament product in the manufacture of a medicament for the treatment or prophylaxis of allergic rhinitis.

8. (original) A method of treatment of allergic rhinitis which comprises administering to a patient a pharmaceutically acceptable amount of a formulation according to claim 1.

9. (currently amended) A process for preparing a formulation according to claim 1, ~~as herein before described by reference to the manufacturing flow diagram shown in Figure 1 comprising the steps of:~~

- a. dissolving propylene glycol in water to produce a liquid formulation 1;
- b. dissolving dextrose in liquid formulation 1 to generate liquid formulation 2;
- c. dissolving phenylethyl alcohol in liquid formulation 2 to generate liquid formulation 3;
- d. dispersing Avicel RC591 in liquid formulation 3 to generate liquid formulation 4;
- e. providing disodium hydrogen orthophosphate anhydrous dissolved in water;
- f. providing citric acid monohydrate dissolved in water;
- g. providing a slurry of micronized beclomethasone dipropionate anhydrate in polyoxethylene (20) sorbitan monooleate dissolved in glycerol;

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- h. providing benzalkonium chloride dissolved in water;
- i. adding the products of steps e, f, g, and h, under agitation, to a liquid formulation comprising the contents of liquid formulation 4, to yield a liquid formulation 5.

Add the following new claims:

- 10. (currently added) The process of claim 9, wherein liquid formulation 4 is permitted to stand for at least 60 minutes to allow for hydration.
- 11. (currently added) The process of claim 9, wherein the slurry of micronized beclomethasone dipropionate anhydrate in polyoxyethylene (20) sorbitan monooleate dissolved in glycerol, is prepared by dissolving said polyoxyethylene (20) sorbitan monooleate in glycerol, and adding micronised beclomethasone dipropionate anhydrate thereto;
- 12. (currently added) The process of claim 11, wherein the polyoxyethylene (20) sorbitan monooleate is dissolved in the glycerol at between 46-50°C.
- 13. (currently added) The process of claim 9 wherein said benzalkonium chloride dissolved in water is presented in a 50% w/v solution.
- 14. (currently added) The process of claim 9, wherein said liquid formulation 5 is subjected to a pH measurement, and if required, the pH is adjusted to between 5 and 6, to generate a liquid formulation 6.
- 15. (currently added) The process of claim 9, wherein said liquid formulation 6 is passed through at least one 100 mesh filter, to generate a liquid formulation 7.
- 16. (currently added) The process of claim 15, wherein said liquid formulation 7 is metered into a suitable delivery device.